

# ATTACHMENT 21

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

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SURGICAL INSTRUMENT SERVICE )  
COMPANY, INC., )  
Plaintiff/ )  
Counter-Defendant )  
vs. ) Case No.  
INTUITIVE SURGICAL, INC., ) 3:21-cv-03496-VC  
Defendant/ )  
Counter-Claimant.)  
-----)

REMOTE VIDEOTAPED DEPOSITION OF  
AMANDEEP MAHAL, M.D.  
Tuesday, March 14, 2023  
Volume I

Reported by:  
NADIA NEWHART, CSR No. 8714  
Job No. 5783327

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Remote videotaped deposition of  
AMANDEEP MAHAL, M.D., Volume I, taken on behalf of  
Defendant/Counter-claimant, with all participants  
appearing remotely via videoconference and the  
witness testifying from Omaha, Nebraska, beginning  
at 9:39 a.m. and ending at 2:14 p.m. on Tuesday,  
March 14, 2023, before NADIA NEWHART, Certified  
Shorthand Reporter No. 8714.

1 use of the Da Vinci robot system for more and more  
2 of the general surgeries that were performed in the  
3 state of Michigan.

4 Q Are the surgeries you do in your current  
5 practice, are they considered general surgery, or 11:31:43  
6 are they considered part of gynecological surgery or  
7 both or neither?

8 I mean, where -- what specialty do you think  
9 they fall into?

10 A So I'm a surgical subspecialist and would 11:31:59  
11 never claim to be a general surgeon. General  
12 surgeons have a very different subset of  
13 specialties.

14 My particular field of interest is  
15 reconstruction and urinary incontinence of the 11:32:14  
16 female pelvis. And so urogynecology falls somewhere  
17 between general gynecology and urology.

18 Q Could you look, please, at paragraph 37. You  
19 say that (as read):

20 "Da Vinci surgery has become a 11:32:38  
21 staple and essential for many  
22 surgeons."

23 What is -- what has become essential about  
24 Da Vinci surgery? Essential means -- what are --  
25 what is your definition of essential in this 11:32:58

1 Q Have you heard that from surgeons?

2 A I have.

3 Q Do you have any reason to doubt the sincerity  
4 of a surgeon who's told you that he or she needs to  
5 have -- to be able to deploy the Da Vinci system in 11:36:08  
6 order to do their surgeries safely?

7 A I wouldn't have any reason to doubt a doctor  
8 who tells me that they require Da Vinci to do a  
9 surgery safely.

10 Q Could you go, please, to paragraph 38. 11:36:20

11 Is it true that in your own practice, the  
12 Da Vinci tool is something that you deem essential  
13 to do certain procedures safely?

14 A I believe the Da Vinci surgery, especially in  
15 the example pointed out here in paragraph 38 for a 11:37:29  
16 sacrocolpopexy, in my hand, there's a safer way to  
17 perform that procedure.

18 Q And that's because of the more precise  
19 movement and better optics afforded by the Da Vinci  
20 system; isn't that right? 11:37:47

21 A That, in addition to the delicate nature of  
22 the area which I'm resecting.

23 Q I'd like to ask you -- I'm going to change  
24 subjects a little bit -- not totally, but I want to  
25 stay on the informed consent for a few more 11:38:25

1 numbers are?

2 A I would be remiss to even guess what the  
3 numbers are.

4 Q Could you look, please, at paragraph 41. And  
5 I'm going to ask you about the sentence which also 11:45:12  
6 includes the first line on page 13. So paragraph 41  
7 spans pages 12 and 13.

8 There's a sentence that begins at the bottom  
9 of page 12, and it completes on the top of page 13.  
10 There's a phrase (as read): 11:45:32

11 "...through hospitals' promotion of  
12 their Da Vinci surgery programs and  
13 through general media or word of  
14 mouth."

15 Do you see that? 11:45:44

16 A I do see that.

17 Q What do you have reference to when you write  
18 about hospitals' promotion of their Da Vinci surgery  
19 programs?

20 A Right around 2019, I believe, two of the 11:45:57  
21 outlying hospitals in Omaha, Nebraska purchased  
22 Da Vinci X and Xi robots. And before that, there  
23 were no options for robotic surgery kind of east of  
24 the Missouri River.

25 After those were purchased, you could see 11:46:19

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1 billboards going down the interstate advertising  
2 the -- you know, the new robotics program that was  
3 available in these two hospitals.

4 And as such, as patients came into my office  
5 in the subsequent months and years, there was more 11:46:36  
6 and more discussion as to this robotic program, it  
7 wasn't something that I was doing, et cetera.

8 Q Is it consistent with your experience to talk  
9 about increasing awareness of robotic surgery as one  
10 of the features of the medical environment these 11:47:04  
11 days?

12 MR. VAN HOVEN: Objection to form.

13 THE WITNESS: When you mean to speak of, do  
14 you mean out in the community with friends? Do you  
15 mean with patients? If you could specify, I could 11:47:18  
16 help answer that.

17 BY MR. RUBY:

18 Q Sure. Just reading paragraph 41 where you  
19 say "robotic surgery becomes more publicly known,"  
20 et cetera, are you writing about a phenomenon that 11:47:34  
21 you would describe as heightened awareness of  
22 robotic surgery and the impact that it might have in  
23 respect to the certain kinds of medical treatment?

24 A I believe that over the last -- or over the  
25 span of my career even, more and more, I receive 11:47:58

1 Q And you also in this paragraph use the word  
2 "service." You used it a couple of times.

3 And what I'd like to do -- and then we'll  
4 take a break -- we can take it now if you want. But  
5 I'd like to get your -- the definition you use for 12:06:34  
6 these terms that appear not infrequently in your  
7 report.

8 So when you say that -- the phrase  
9 "laparoscopic instruments that have been  
10 serviced" -- that's in that paragraph -- what does 12:06:53  
11 it mean to you, as the author, that has been done to  
12 that laparoscopic instrument? It's had a paint job?  
13 It's been sanded? It's been replanted?

14 I'm not trying to make light of this, but it  
15 will save time if we have a common vocabulary so -- 12:07:08

16 A All right.

17 Q -- what's --

18 A Sorry, I cut you off. I said I wouldn't. Go  
19 ahead.

20 Q No. So what does it mean to you, as the 12:07:17  
21 author of this, to say that an instrument has been  
22 repaired? What has -- what has been done to that  
23 instrument in your use of that term?

24 A So this report I put together based on, like  
25 I said, the materials that I've reviewed, as well as 12:07:39



1 my own clinical experience.

2 And when I say that I know that hospitals  
3 sometimes send out their instruments for, you know,  
4 whatever, retooling, repair, refurbish, what I mean  
5 by that is, I have said or the hospital has decided 12:07:54  
6 that an instrument is not functioning up to what it  
7 needs to and it needs to go out for repair work.

8 But throughout the report, I do tend to use  
9 the term "serviced," "repaired," "refurbished"  
10 somewhat interchangeably, because to me, as a 12:08:13  
11 practicing surgeon, it doesn't -- it doesn't -- it  
12 doesn't affect the end use of the product for me.  
13 And those terms kind of don't have a lot of the  
14 bearing to my actual practice.

15 Q Before you begin a surgery using the Da Vinci 12:08:27  
16 tools, do you personally conduct any kind of  
17 pre-operative check or inspection of the  
18 instruments?

19 A Before I start a surgery, I ask to look at  
20 the panel of tools that have been given to me. But 12:09:00  
21 before starting the surgery, I don't do any specific  
22 control check on the instruments themselves other  
23 than to make sure they are available in the  
24 operating room.

25 Q What is a panel of tools? I'm sorry I 12:09:13

1 A Yes.

2 Q Is -- strike that.

3 In your first report, is the term

4 "malfunctioning EndoWrist" synonymous with failure,

5 as you use those terms?

12:50:40

6 A Certainly, in the context of paragraph 61,

7 I'm using those two terms interchangeably so that --

8 those end uses where a malfunction or a failure

9 happens.

10 Q Would you look, please, at paragraph 62, and

12:50:59

11 in particular, the last sentence.

12 A Okay. Starting with, "Given the nearly

13 identical operation"?

14 Q Yes.

15 A I do see it.

12:52:39

16 Q All right. Were you asked in this engagement

17 to make any assumptions about what process would be

18 undertaken with instruments by a third-party vendor

19 if there were no usage counters?

20 A I'm not sure if I was asked specifically

12:53:16

21 about if there were no usage counters, but I did ask

22 to see any documentation or get an understanding of

23 what would be involved in this kind of repair

24 process, at least from a high level.

25 Q And what did you take away from that?

12:53:34

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1        what -- what assumption did you make about what  
2        would be done in what you call this high-level  
3        repair process?

4                MR. VAN HOVEN:    Objection to form.

5                THE WITNESS:    Yeah, I would say with my --                12:53:48  
6        with my high-level review of the -- of the  
7        evaluation and the repair process that would be  
8        performed, it appeared that there was a very well  
9        thought out and standardized approach to evaluating  
10       even some of the more small components or pieces of                12:54:06  
11       the EndoWrist devices and that they seemed to be a  
12       reasonable way of going about the repair, though I  
13       myself am not a, you know, engineering expert to  
14       review those papers with any kind of technical  
15       aspects.    12:54:23

16       BY MR. RUBY:

17               Q     Well, did your study or evaluation of the  
18       materials that were furnished to you that purported  
19       to tell you about the content of the repair, so  
20       called, what specifically did you think would be                12:54:54  
21       done on the issue of -- excuse me -- sharpening of  
22       the instruments?

23               A     My -- again, without perfect recollection of  
24       all those documents, it sounded like --

25               Q     Sorry.    12:55:08

1 MR. VAN HOVEN: Objection to form.

2 THE WITNESS: Again, I wouldn't -- I don't  
3 recall the specifics about what to do with broken  
4 pieces or parts.

5 BY MR. RUBY: 12:57:24

6 Q You did see some materials, did you not, that  
7 spoke about tensioning of the cables, getting the  
8 tension correct?

9 A I believe there was discussion of tensioning  
10 of the cables within those documents. 12:57:53

11 Q All right. And did you take away from your  
12 reading of it that in some fashion, the cables going  
13 through the quote/unquote repair process, were  
14 supposed to be evaluated for the correct tension in  
15 the cables, and if it was incorrect, that they would 12:58:17  
16 be properly tensioned? Is that, from a high level,  
17 what they said?

18 A That's my understanding of how they were  
19 going about the repair.

20 But again, here, my goal was not to 12:58:33  
21 understand every piece or aspect of the repair  
22 process that was being done but to see if there was,  
23 for the most part, a comprehensive review from what  
24 I worried about, as far as looking at those  
25 instruments and seeing if they were appropriate to 12:58:55

1 be put back in use.

2 Q Could go, please, to paragraph 72.

3 A Sure.

4 Q I mean, is this -- strike that.

5 Does paragraph 72 summarize some of the 01:00:13

6 concepts you've been explaining to me for the last

7 few minutes? You were looking for quality

8 standards, and you were looking to get information

9 about how those standards were going to be met if a

10 third-party vendor was part of the process? 01:00:41

11 MR. VAN HOVEN: Objection to form.

12 THE WITNESS: I think paragraph 72 helps to

13 summarize the goal and in some ways the lens of

14 which I use to prepare this report, which was to

15 think of myself as someone who was asked to use 01:01:02

16 these instruments, what would I want to know about

17 and would these be things that I would be

18 comfortable using?

19 And like all instruments that I use, I rely

20 on the hospital system to go through their usual 01:01:17

21 forms and go through their usual kind of safety

22 checks to provide me with instruments that are

23 appropriate for use in the OR.

24 Q If you'd look, please, at the -- did I give

25 you a chance to read through paragraph 72 to 01:01:56

1 Exhibit 285 or should I take it off the Veritext?

2 Q 285 is the complaint? You can put it aside  
3 for now.

4 A Thank you.

5 Q Yeah. Oh, and -- yes. 01:37:35

6 A Yeah, I've got 33 in front of me.

7 Q Okay. Is RAS an abbreviation for  
8 robotic-assisted surgery?

9 A Yes.

10 Q In the substance of paragraph 33, you opine 01:38:04  
11 that (as read):

12 "...some surgeons have gone to  
13 offering only RAS and would convert  
14 to open surgery if there was an  
15 issue during the procedure. In such 01:38:30  
16 instances, laparoscopic surgery  
17 would not be an option."

18 What is your basis for this opinion?

19 A My basis is my experience with the surgeons  
20 in the surrounding community of Omaha and that some 01:38:48  
21 of them have taken to relying on the robot for most,  
22 if not all, of their surgeries and would be unable  
23 to convert to a laparoscopic surgery in those  
24 instances.

25 Q Would you look, please, at paragraph 36. 01:39:02

1 into the -- you know, the minutia of trans identity  
2 and how we address those kind of situations.

3 And then the final four years of my training  
4 was, again, exclusively on females for  
5 reconstructive surgery. 01:46:17

6 Q In terms of superiority of the Da Vinci  
7 technique and tools, as you've testified to it  
8 already today, do you perceive any differences in  
9 the gender of patients? Is the robot more  
10 important, in your opinion, to the surgical 01:46:39  
11 treatment of men than women or women than men?

12 A I think it would be equally important for  
13 both men and women given some gender-specific  
14 surgeries that are now performed more frequently  
15 with the robot, prostatectomy being one I gave an 01:47:01  
16 example of in my report.

17 Q What is the basis for your opinion that the  
18 Si and Xi systems provide similar advantages for  
19 most surgery?

20 A The basis of the opinion -- and, again, it's 01:47:38  
21 not all-encompassing -- comes from my own clinical  
22 experience with both the S, the Si, as well as the X  
23 and Xi platforms while out in independent practice.

24 And as the hospitals around my community  
25 changed over from Si to X and Xi platforms, I do not 01:47:52

1 clinically see a difference in my operative times,  
2 the rare but possible complications or the setup  
3 times for myself with surgery, as well as the other  
4 surgeons in the community that I spoke with.

5 Q Would you look, please, again, at 01:48:13  
6 paragraph 62 in your first report.

7 A Yeah, I'm seeing it.

8 Q Okay. Now, you say in paragraph 62 (as  
9 read):

10 "...there is no reason to believe 01:49:04  
11 that an EndoWrist instrument that  
12 has been serviced after expiration  
13 of the Intuitive specified use  
14 counter would not operate in the  
15 same manner as an EndoWrist whose 01:49:16  
16 use counter has not expired."

17 What's the basis for that opinion, please?

18 A So I've based this opinion based on a review  
19 of the documents that were provided for me; and in  
20 addition, my own surgical practice and understanding 01:49:35  
21 of failures that have been reported at the hospital.

22 Q Have you ever done surgery with an EndoWrist  
23 instrument beyond its tenth surgery?

24 A I have not done surgery past that expiration  
25 date, but I have experienced failures and problems 01:50:08



1 with EndoWrist within their expiration counters.

2 Q Did you ever -- strike that.

3 Have you ever read or read the contents of  
4 testing, if any, done by Intuitive beyond ten uses  
5 of EndoWrist instruments?

01:50:44

6 A I am aware that there has been testing done,  
7 though I'm not sure -- well, I am sure that I've  
8 never seen that data through my work with this case  
9 or elsewhere as far as like training or exercising  
10 devices to a fatigue or a failure point.

01:51:03

11 Q Have you asked anybody to let you see those  
12 tests, test results?

13 A In the basis of forming my opinion, I asked  
14 to see what kind of testing was performed by  
15 Intuitive. And I was given information that I've  
16 cited in my work and my expert opinion. Most of  
17 those tests were done up to the typical use of --  
18 you know, I believe it's ten uses for most of them.

01:51:23

19 I do recall a specific example where there  
20 was a deposition of a person who mentioned testing  
21 that went beyond that during the engineering phase  
22 of the EndoWrist instruments.

01:51:40

23 Q Do you consider yourself an expert in the  
24 formatting and evaluation of failure testing of  
25 medical devices?

01:52:06

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1           A    I am not an expert in the testing and failure  
2           testing, nor am I an expert in the statistics that  
3           go along with that. I simply used those paragraphs  
4           and that information to inform what I already know  
5           about the fail rate and the use of these products           01:52:23  
6           for the end user, namely, the surgeon and the  
7           patient.

8           Q    What is off-label usage of a medical device,  
9           generally?

10          A    Right. To just couch that, even though           01:53:07  
11          you've already said "generally," I am not an expert  
12          in the FDA. But what I would say is when the FDA  
13          clears certain devices or medicines, they often do  
14          so with labeling or information regarding the use or  
15          why this was approved.           01:53:25

16                If at any point a medicine is used outside of  
17          those confines or a device is used outside of those  
18          confines, that would be considered off-label use,  
19          which happens throughout medical practice.

20          Q    What importance, if any, do you assign to           01:53:48  
21          the -- the presence or absence of FDA clearance for  
22          a particular use of a medical device?

23                MR. VAN HOVEN: Objection to form.

24                THE WITNESS: I think that FDA clearance for  
25          a medical device is something that we use and know           01:54:12